

CLAIMS:

- 1 1. A tissue separator assembly comprising:
  - 2 a proximal end assembly;
  - 3 a catheter assembly, extending from the proximal end assembly, comprising:
    - 4 a shaft having a distal portion and defining an axis at the distal portion;
    - 5 and
    - 6 an elongate tissue separator element having a proximal part and a distal part, the distal part connected to the distal portion of the shaft and movable between a retracted state, adjacent to the distal portion, and an outwardly extending, operational state; and
    - 7 the proximal end assembly comprising a first driver, operably coupled to the tissue separator element, constructed to (1) move the tissue separator element from the retracted state to the operational state, and (2) automatically rotate the tissue separator element about the axis, whereby a tissue section is separable from surrounding tissue by the moving tissue separator element.
- 10 2. The assembly according to claim 1 wherein the first driver is constructed to automatically rotate the tissue separator element after the tissue separator element is in the operational state.
- 11 3. The assembly according to claim 1 wherein first driver automatically rotates the shaft and the tissue separator element therewith about the axis.
- 12 4. The assembly according to claim 1 wherein the shaft has at least one longitudinally extending bore.
- 13 5. The assembly according to claim 1 wherein the catheter assembly comprises a hollow introducer sheath housing the shaft.
- 14 6. The assembly according to claim 1 wherein the distal part of the tissue separator element comprises a wire.

1      7.      The assembly according to claim 1 wherein the distal part of the tissue separator element  
2      bows outwardly when in the operational state.

1      8.      The assembly according to claim 1 further comprising an energy source selectively  
2      coupled to the tissue separator element.

1      9.      The assembly according to claim 8 wherein the energy source comprises an RF generator.

1      10.     The assembly according to claim 1 wherein the first driver comprises an actuator  
2      movable along a path from a first position, to a second position and to a third position, said  
3      actuator comprising a first part engageable with the proximal part of the tissue separator element  
4      as the actuator moves between the first and second positions so to move the distal part of the  
5      tissue separator element from the retracted state to the operational state.

1      11.     The assembly according to claim 10 wherein the first driver comprises a lead screw  
2      rotationally coupled to the shaft so rotation of the lead screw causes the shaft to rotate.

1      12.     The assembly according to claim 11 wherein the lead screw comprises a rotary position  
2      indicator.

1      13.     The assembly according to claim 12 wherein the lead screw has a proximal end and the  
2      proximal end the comprises said indicator.

1      14.     The assembly according to claim 11 wherein the first driver comprises a lead nut  
2      rotationally mounted to the lead screw, said lead nut and lead screw configured so that axial  
3      movement of the lead nut causes rotational movement of the lead screw and the shaft therewith.

1      15.     The assembly according to claim 14 wherein the actuator comprises a second part  
2      engageable with the lead nut as the actuator moves from the second position to the third position  
3      thereby causing the lead screw and the shaft and tissue separator element therewith to rotate.

1 16. The assembly according to claim 1 wherein the catheter assembly comprises a tissue  
2 section holding element at the distal portion of the shaft, said holding element movable from a  
3 retracted condition to an extended, tissue engaging condition so to help secure a separated tissue  
4 section to the catheter assembly.

1 17. The assembly according to claim 16 wherein the tissue section holding element  
2 comprises at least one wire having a pre-curved distal end.

1 18. The assembly according to claim 16 wherein the proximal end assembly comprises a  
2 second driver, operably coupled to the holding element, constructed to move the holding element  
3 from the retracted condition to the extended, tissue engaging condition.

1 19. The assembly according to claim 1 wherein the catheter assembly comprises a tubular  
2 braided element at the distal portion of the shaft movable longitudinally and radially between a  
3 proximal, radially contracted state and a distal, radially expanded state with said tubular braided  
4 element surrounding the tissue separator element and any separated tissue section when in the  
5 distal, radially expanded state.

1 20. They assembly according to claim 19 wherein the shaft comprises an outwardly flaring  
2 guide surface to help guide the tubular braided element along a tissue dissection between a  
3 separated tissue section and surrounding tissue as the tubular braided element moves from the  
4 proximal, radially contracted state to the distal, radially expanded state.

1 21. The assembly according to claim 19 wherein the proximal end assembly comprises a  
2 second driver, operably coupled to the tubular braided element, constructed to move the tubular  
3 braided element from the proximal, radially contracted state to the distal, radially expanded state.

1 22. The assembly according to claim 1 wherein the catheter assembly comprises:  
2 a tissue section holding element at the distal portion of the shaft, said holding  
3 element movable from a retracted condition to an extended, tissue engaging condition so  
4 to help secure a separated tissue section to the catheter assembly; and

5                   a tubular braided element at the distal portion of the shaft movable longitudinally  
6                   and radially between a proximal, radially contracted state and a distal, radially expanded  
7                   state with said tubular braided element surrounding the tissue separator element and any  
8                   separated tissue section when in the distal, radially expanded state.

1   23.   The assembly according to claim 27 wherein the proximal end assembly comprises a  
2   second driver, operably coupled to the holding element and to the tubular braided element,  
3   constructed to:

4                   move the holding element from the retracted condition to the extended, tissue  
5                   engaging condition and;

6                   move the tubular braided element from the proximal, radially contracted state to  
7                   the distal, radially expanded state.

1   24.   The assembly according to claim 23 wherein the second driver is a manually operated  
2   driver.

1   25.   A tissue separator assembly comprising:

2                   a proximal end assembly;

3                   a catheter assembly, extending from the proximal end assembly, comprising:

4                   a shaft having a distal portion and defining an axis at the distal portion;  
5                   and

6                   an elongate tissue separator element having a proximal part and a distal  
7                   part, the distal part connected to the distal portion of the shaft and movable  
8                   between a retracted state, adjacent to the distal portion, and an outwardly bowed,  
9                   operational state;

10                  an energy source selectively coupled to the tissue separator element;

11                  the proximal end assembly comprising a first driver, operably coupled to the  
12                  tissue separator element, constructed to (1) move the tissue separator element from the  
13                  retracted state to the operational state, and thereafter (2) automatically rotate the tissue  
14                  separator element about the axis, whereby a tissue section is separable from surrounding  
15                  tissue by the moving tissue separator element;

16                  the catheter assembly comprising:

17                   a tissue section holding element at the distal portion of the shaft, said  
18                   holding element movable from a retracted condition to an extended, tissue  
19                   engaging condition so to help secure a separated tissue section to the catheter  
20                   assembly;

21                   a tubular braided element at the distal portion of the shaft movable  
22                   longitudinally and radially between a proximal, radially contracted state and a  
23                   distal, radially expanded state with said tubular braided element surrounding the  
24                   tissue separator element and any separated tissue section when in the distal,  
25                   radially expanded state; and

26                   the proximal end assembly comprising a second driver, operably coupled  
27                   to the holding element and to the tubular braided element, constructed to:

28                   move the holding element from the retracted condition to the  
29                   extended, tissue engaging condition; and

30                   move the tubular braided element from the proximal, radially  
31                   contracted state to the distal, radially expanded state.

1           26. The assembly according to claim 25 wherein:

2                   the first driver comprises an actuator movable along a path from a first position,  
3                   to a second position and to a third position, said actuator comprising a first part  
4                   engageable with the proximal part of the tissue separator element as the actuator moves  
5                   between the first and second positions so to move the distal part of the tissue separator  
6                   element from the retracted state to the operational state;

7                   the first driver comprises a lead screw rotationally coupled to the shaft so rotation  
8                   of the lead screw causes the shaft to rotate;

9                   the first driver comprises a lead nut rotationally mounted to the lead screw, said  
10                  lead nut and lead screw configured so that axial movement of the lead nut causes  
11                  rotational movement of the lead screw; and

12                  the actuator comprises a second part engageable with the lead nut as the actuator  
13                  moves from the second position to the third position thereby causing the lead screw and  
14                  the shaft and tissue separator element therewith to rotate.

1           27. A tissue separator assembly comprising:

2 a proximal end assembly;  
3 a catheter assembly, extending from the proximal end assembly, comprising:  
4 a shaft having a distal portion and defining an axis at the distal portion;  
5 and  
6 tissue separator means, at the distal portion of the shaft and movable  
7 between a retracted state and an extended, operational state, for passing through  
8 and separating tissue;  
9 the proximal end assembly comprising means for (1) moving the tissue separator  
10 means from the retracted state to the extended, operational state, and (2) automatically  
11 rotating the tissue separator element about the axis, whereby a tissue section is separable  
12 from surrounding tissue.

28. The assembly according to claim 27 wherein the catheter assembly comprises means for  
helping to secure a separated tissue section to the catheter assembly.

29. The assembly according to claim 27 wherein the catheter assembly comprises means for  
selectively enveloping the distal portion of the shaft, the tissue separator means and any  
separated tissue section.

30. A tissue separator assembly comprising:  
2 a proximal end assembly;  
3 a catheter assembly, extending from the proximal end assembly, comprising:  
4 a shaft having a distal portion and defining an axis at the distal portion;  
5 and  
6 a movable tissue separator element at the distal portion of the shaft;  
7 the proximal end assembly comprising a first driver, operably coupled to the  
8 tissue separator element, constructed to drive the tissue separator element through tissue  
9 to separate a tissue section from surrounding tissue;  
10 the catheter assembly comprising:  
11 a tissue section holding element at the distal portion of the shaft, said  
12 holding element movable from a retracted condition to an extended, tissue

engaging condition so to help secure a separated tissue section to the catheter assembly;

a tubular braided element at the distal portion of the shaft movable longitudinally and radially between a proximal, radially contracted state and a distal, radially expanded state with said tubular braided element surrounding the tissue separator element and any separated tissue section when in the distal, radially expanded state; and

the proximal end assembly comprising a second driver, operably coupled to the holding element and to the tubular braided element, constructed to:

move the holding element from the retracted condition to the extended, tissue engaging condition; and

move the tubular braided element from the proximal, radially contracted state to the distal, radially expanded state.

31. The assembly according to claim 30 wherein the first driver is constructed to automatically rotate the shaft and the tissue separator element therewith about the axis after the tissue separator element is in the operational state.

32. The assembly according to claim 30 wherein the shaft has at least one longitudinally extending bore.

1 33. The assembly according to claim 30 wherein the catheter assembly comprises a hollow  
2 introducer sheath housing the shaft.

1 34. The assembly according to claim 30 wherein the distal part of the tissue separator  
2 element comprises a wire.

1 35. The assembly according to claim 30 further comprising an energy source selectively  
2 coupled to the tissue separator element.

1 36. The assembly according to claim 35 wherein the energy source comprises an RF  
2 generator.

1 37. The assembly according to claim 30 wherein the first driver comprises an actuator  
2 movable along a path from a first position, to a second position and to a third position, said  
3 actuator comprising a first part engageable with the proximal part of the tissue separator element  
4 as the actuator moves between the first and second positions so to move the distal part of the  
5 tissue separator element from the retracted state to the operational state.

1 38. They assembly according to claim 37 wherein the first driver comprises a lead screw  
2 rotationally coupled to the shaft so rotation of the lead screw causes the shaft to rotate.

1 39. The assembly according to claim 38 wherein the lead screw comprises a rotary position  
2 indicator.

1 40. The assembly according to claim 39 wherein the lead screw has a proximal end and the  
2 proximal end the comprises said indicator.

1 41. The assembly according to claim 38 wherein the first driver comprises a lead nut  
2 rotationally mounted to the lead screw, said lead nut and lead screw configured so that axial  
3 movement of the lead nut causes rotational movement of the lead screw and the shaft therewith.

1 42. The assembly according to claim 41 wherein the actuator comprises a second part  
2 engageable with the lead nut as the actuator moves from the second position to the third position  
3 thereby causing the lead screw and the shaft and tissue separator element therewith to rotate.

1 43. The assembly according to claim 30 wherein the tissue section holding element  
2 comprises at least one wire having a pre-curved distal end.

1 44. They assembly according to claim 30 wherein the shaft comprises an outwardly flaring  
2 guide surface to help guide the tubular braided element along a tissue dissection between a  
3 separated tissue section and surrounding tissue as the tubular braided element moves from the  
4 proximal, radially contracted state to the distal, radially expanded state.

1 45. The assembly according to claim 30 wherein the second driver is a manually operated  
2 driver.

1 46. A tissue separator assembly comprising:  
2 a proximal end assembly;  
3 a catheter assembly, extending from the proximal end assembly, comprising tissue  
4 separator means for passing through and separating tissue;  
5 the proximal end assembly comprising a first driving means for driving the tissue  
6 separator means through tissue to separate a tissue section from surrounding tissue;  
7 the catheter assembly comprising;  
8 tissue puncturing means for helping to secure a separated tissue section to  
9 the catheter assembly; and  
10 means for surrounding the tissue separator means and any separated tissue  
11 section; and  
12 the proximal end assembly comprising a second driving means for:  
13 driving the tissue puncturing means into a separated tissue section; and  
14 driving the surrounding means.

1 47. A method for creating a tissue section within surrounding tissue comprising:  
2 positioning a distal end of a catheter assembly at a target location within a patient,  
3 the catheter assembly defining an axis;  
4 moving an elongate tissue separator element, at the distal end of the catheter  
5 assembly, from a radially retracted state to an outwardly extending, operational state; and  
6 automatically, following at least the start of the separator element moving step,  
7 rotating the separator element about the axis to separate a tissue section from surrounding  
8 tissue.

1 48. The method of according to claim 47 further comprising supplying energy to the  
2 separator element.

1 49. The method of according to claim 48 wherein the energy supplying step comprises  
2 supplying RF energy to the separator element.

1 50. The method of according to claim 47 wherein the automatically rotating step begins after  
2 the separator element has reached the operational state.

1 51. The method according to claim 47 wherein the automatically rotating step is carried out  
2 by rotating the separator element about 540° about the axis.

1 52. The method according to claim 47 further comprising moving a tissue holding element,  
2 located at the distal end of the catheter assembly, from a retracted condition to an extended,  
3 tissue engaging condition.

1 53. The method according to claim 52 wherein the tissue holding element moving step is  
2 carried out following the automatically rotating step.

54. The method according to claim 52 wherein the tissue holding element moving step is carried out using at least one wire having a pre-curved distal end.

55. The method according to claim 47 further comprising surrounding the separated tissue section with a tubular braided element by moving the tubular braided element, located at the distal end of the catheter assembly, from a proximal, radially contracted state to a distal, radially expanded state following the automatically rotating step.

1 56. A method for creating a tissue section within surrounding breast tissue of a patient  
2 comprising:

positioning a distal end of a catheter assembly at a target location within the breast of a patient, the catheter assembly defining an axis;

moving an elongate tissue separator element, at the distal end of the catheter assembly, from a radially retracted state to a radially extended, outwardly bowed, operational state;

supplying energy to the separator element;

automatically, following the separator element moving step, rotating the separator element about the axis to separate a tissue section from surrounding tissue;

11 moving a tissue holding element, located at the distal end of the catheter  
12 assembly, from a retracted condition to an extended, tissue engaging condition; and  
13 surrounding the separated tissue section with the tubular braided element by  
14 moving the tubular braided element, located at the distal end of the catheter assembly,  
15 from a proximal, radially contracted state to a distal, radially expanded state following  
16 the automatically rotating step.

1 57. The method of according to claim 56 wherein the energy supplying step comprises  
2 supplying RF energy to the separator element.

1 58. The method of according to claim 56 wherein the automatically rotating step begins after  
2 the separator element has reached the operational state.

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59. The method according to claim 56 wherein the automatically rotating step is carried out by rotating the separator element about  $540^\circ$  about the axis.

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60. The method according to claim 56 wherein the tissue holding element moving step is carried out following the automatically rotating step.

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61. The method according to claim 56 wherein the tissue holding element moving step is carried out using at least one wire having a pre-curved distal end.